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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,563	06/30/2004	Pascale Laroche	0523-1015	5207
466	7590	06/01/2007		
YOUNG & THOMPSON 745 SOUTH 23RD STREET 2ND FLOOR ARLINGTON, VA 22202			EXAMINER VENC, DAVID J	
			ART UNIT	PAPER NUMBER
			1641	
			MAIL DATE	DELIVERY MODE
			06/01/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/500,563

Applicant(s)

LAROCHE, PASCALE

Examiner

David J. Venci

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on February 28, 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 20-38 is/are pending in the application.
- 4a) Of the above claim(s) 26-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 20-38 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on June 30, 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 06/30/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Examiner acknowledges Applicant's election with traverse of Invention I, claims 20-25. However, Applicant did not distinctly and specifically point out the supposed errors in the restriction requirement. Applicant's election is treated as an election without traverse (MPEP § 818.03(a)) and is made FINAL.

Claims 26-38 are drawn to non-elected inventions and are withdrawn from further consideration pursuant to 37 CFR 1.142(b), there being no allowable generic or linking claim. Currently, claims 20-25 are under examination.

Specification

The disclosure is objected to because of the following "informalities":

1. On p. 17, lines 36-37, the phrase "The system of sensitized particles used in the examples below belongs to the Luminex® system" is indefinite because the exact identities (e.g., catalog numbers, batch numbers, alternate tradenames or descriptions, etc.) of said "sensitized particles" is not clear and appears omitted from the specification.
2. On p. 18, line 4, the phrase "a flow cytometer interfaced with a computer system" is indefinite because the exact identities (e.g., manufacturers, models, software versions, etc.) of said cytometer and computer system is not clear and appears omitted from the specification.
3. On p. 18, line 6, the phrase "a first laser" is indefinite because the exact identity (e.g., manufacturer, model, wavelength, serial no., etc.) of said laser is not clear and appears omitted from the specification.

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4. On p. 18, line 9, the term "external" is indefinite because the exact identity of one or more points of reference required for ascertaining "external" or not "external" is not clear and appears omitted from the specification.
5. On p. 18, line 10, the term "fluorescent compound" is indefinite because the exact identity (*e.g.*, name, structure, synthetic protocol, manufacturer, batch number, etc.) of said "fluorescent compound" is not clear and appears omitted from the specification.
6. On p. 18, lines 22-23, the phrase "colored polystyrene particles functionalized with COOH groups" is indefinite because the exact identities (*e.g.*, synthetic protocol, manufacturer, catalog numbers, batch numbers, alternate tradenames or descriptions, etc.) of said "colored polystyrene particles" is not clear and appears omitted from the specification. Whether the phrase "colored polystyrene particles functionalized with COOH groups" references the phrase "The system of sensitized particles used in the examples below belongs to the Luminex® system" recited on p. 17, lines 36-37 is not clear.
7. On p. 19, lines 1-2, the phrase "as described above" is indefinite because the exact identity of one or more locations in Applicant's specification referenced by the phrase "as described above" is not clear.
8. On p. 19, in the table, the phrase "Nature of the antigen" is indefinite because the exact identity of one or more standards for ascertaining "Nature" is not clear and appears omitted from the specification. Whether the phrase "Nature" references "philosophy"¹ is not clear.
9. Throughout the specification, the terms "SSA", "SSB", "Sm", "Sm/NRP", "ScI70" and "Jo1" are indefinite because the exact identity of one or more objects referenced by each abbreviated term lacks antecedent basis.
10. Throughout the specification, the terms "SSA antigen" and "SSB antigen" are indefinite because the exact identity of one or more objects referenced by the terms "SSA antigen" and "SSB antigen" is not clear and appears omitted from the specification.

¹ See *infra*, note 2 and referencing text.

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11. On p. 20, lines 13-14, the phrase "concentration of 150 μ g" is indefinite because the phrase does not correspond to any art-recognized concentration parameter.
12. On p. 20, line 15, the phrase "concentration of 300 μ g" is indefinite because the phrase does not correspond to any art-recognized concentration parameter.
13. On p. 20, line 16, the phrase "the antigen-antibody reaction" lacks antecedent basis.
14. On p. 20, line 17, the phrase "concentration of 75 μ g" is indefinite because the phrase does not correspond to any art-recognized concentration parameter.
15. On p. 20, line 25, the phrase "concentration of 100 μ g" is indefinite because the phrase does not correspond to any art-recognized concentration parameter.
16. On p. 20, line 27, the phrase "concentration of 25 μ g" is indefinite because the phrase does not correspond to any art-recognized concentration parameter.
17. On p. 21, line 4, the phrase "as indicated above" is indefinite because the exact identity of one or more locations in Applicant's specification referenced by the phrase "as indicated above" is not clear.

Appropriate correction is required.

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Drawings

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The drawings are objected to because the drawings are missing axes labels.

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Claim Rejections - 35 USC § 101

Section 101 of 35 U.S.C. reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 20-25 are rejected under 35 U.S.C. 101 because the claimed invention lacks patentable utility.

Independent claim 20 is directed to a method of preparing an immunoreagent requiring, *inter alia*, a step of measuring an unidentified "response" within a "known measurement range" of an unidentified analyte (see claim 20, step a).

Applicant asserts his calibration method is specifically useful for decreasing reagent consumption and decreasing overloading titration plates (see specification, paragraph bridging pp. 2-3).

According to M.P.E.P. 2107.02, Office determination of the credibility of Applicants' assertion of utility is based on whether the facts upon which Applicants' assertion is based are inconsistent with the logic underlying Applicants' assertion. In other words, credibility refers to the reliability of Applicants' assertion of utility in view of the logic and facts that Applicants offer to support Applicants' assertion of utility.

Here, Applicant's asserted utilities are not credible because Examiner is unable to locate any substantiation, or even an attempt to substantiate, any of Applicant's specifically asserted utilities anywhere in Applicant's specification. In other words, Applicant's specification fails to disclose any data pertaining to Applicant's reagent consumption, much less data tending to show a decrease in Applicant's reagent consumption directly resulting from Applicant practicing his own invention. In addition, Applicant's specification fails to disclose any data pertaining to Applicant's tendency to overload titration plates (with or without reagent consumption), much less data tending to show a decrease in Applicant's

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tendency of overloading titration plates directly resulting from Applicant practicing his own invention. Aside from the brief mentioning in the paragraph bridging pp. 2-3, the remainder of Applicant's specification appears to have little to do with Applicant's stated intention of decreasing reagent consumption and decreasing overloading titration plates.

Furthermore, Applicant's asserted utilities are not credible because Applicant does not disclose any data pertaining to a measurement of a "response" within a "known measurement range" of an analyte, as recited in claim 20, step a. Example 1 discloses a fluorescence "response" within a range of hypothetical, pretend, imaginary "biological units" (see e.g., paragraph bridging pp. 19-20; see also, Figs. 1 and 2), but no "known measurement range" of any particular analyte. Examples 2 and 3 disclose a something something based on the hypothetical, pretend, imaginary "biological units" of Example 1, and are accordingly hypothetical, pretend and imaginary.

A patent must relate to the world of commerce, not the realm of philosophy, and is not a hunting license.²

² *Brenner, Comr. Pats. v. Manson*, 148 USPQ 689, 696 (US 1966).

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Claim Rejections - 35 USC § 112 – first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 20-25 are rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a credibly asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not want to know how to use the claimed invention.

Claim Rejections - 35 USC § 112 – second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 20-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 20:

The transition phrase "it comprises the steps which consist in" is indefinite because. Whether Applicant intends an open or closed claim is not clear.

In step a), the phrase "homologous compound" is indefinite because the exact identity of one or more objects referenced by the phrase "homologous compound" is not clear. Whether said phrase references any of antecedent "ligand" AND/OR/XOR "analytes" is not clear.

In step a), the phrase "the known measurement range of the analyte" lacks antecedent basis in claim 20 and antecedent support in the specification.

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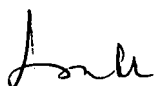
Conclusion

No claims are allowable at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Venci whose telephone number is 571-272-2879. The examiner can normally be reached on 08:00 - 16:30 (EST). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

David J Venci
Examiner
Art Unit 1641

djv


LONG V. LE 05/29/07
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